Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparing the effect of low level laser and pulsed ultrasound on sinus mucus inflammation using fractional exhaled nitric oxide in patients with chronic rhinosinusitis (CRS)

Protocol summary

Study aim

Comparing the effect of low level laser (LLL) and pulsed ultrasound (PUS) on sinus mucus inflammation using fractional exhaled nitric oxide (FeNo) in patients with chronic rhinosinusitis (CRS)

Design

Randomize clinical trial, single blind with parallel groups and one-month follow-up, randomization by Stratified Permuted Block method. The sample size was obtained by using G-power software in each group of 20 people

Settings and conduct

The study will be conducted on 40 patients with CRS who have referred to the Rehabilitation School of Tehran University of Medical Sciences. Patients with inclusion criteria will be randomly divided to one of the two groups of PUS and LLL by selecting a sealed envelope by the clinic secretary after the initial evaluation. 5 treatment sessions are done every day. The research is done single blind and the evaluator will be unaware of the type of treatment of the patients.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 18-65 years, no facial surgery and malignant facial tumor, no polyps, asthma and respiratory diseases. Exclusion criteria: acute recurrent of rhinosinusitis during treatment

Intervention groups

Five sessions of PUS treatment are performed daily on the affected sinuses in the patients of the first intervention group and five sessions of LLL treatment are performed on the affected sinuses in the patients of the second intervention group. This study does not have a control group.

Main outcome variables

SNOT22 questionaire FeNo test Scoring the symptoms based on the sinus scan stereotype

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230805059035N1**
Registration date: **2023-09-15, 1402/06/24**
Registration timing: **prospective**

Last update: **2023-09-15, 1402/06/24**
Update count: **0**

Registration date

2023-09-15, 1402/06/24

Registrant information

Name

Mina Kashi Alashti

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 7703 2824

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-02, 1402/07/10

Expected recruitment end date

2023-12-01, 1402/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparing the effect of low level laser and pulsed ultrasound on sinus mucus inflammation using fractional exhaled nitric oxide in patients with chronic rhinosinusitis (CRS)

Public title
Comparring the effect of laser and ultrasound on sinus mucus inflammatin in patients with chronic rhinosinusitis (CRS)
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with chronic rhinosinusitis; The duration of infection is between 3 months and a maximum of 5 years
Exclusion criteria:
Not having polyp and sinus retention cyst No history of facial surgery No malignant lesions in the head and neck area Not having asthma and respiratory diseases
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
The randomization in this study will be by the Stratified Permuted Block Randomization method, in which people are divided into two groups (ultrasound treatment group and laser treatment group) after meeting the conditions for entering the study. For this purpose, first, by Random Allocation computer software (version 1.1, Isfahan University of Medical Sciences, Iran), a random order of two letters A (ultrasound treatment) and B (laser treatment) in blocks with random numbers of 4 and 6 (for example ABBA and ABAABB are made. Then the blocks are hidden by non-transparent envelopes. In order to minimize the selection bias and ensure the concealment of the allocation of people in the groups, the randomization process is done by a person who is not in any of the other stages of the research. In this way, patients are randomly placed in one of the two groups (pulsed ultrasound treatment or low power laser treatment).
Blinding (investigator's opinion)
Single blinded
Blinding description
The evaluator will be unaware of the type of treatment of the patients.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciences
Street address
School of Rehabilitation of Tehran University of Medical Sciences, Pich Shemiran, Islamic Revolution St, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
65111-11489
Approval date
2023-08-16, 1402/05/25
Ethics committee reference number
IR.TUMS.FNM.REC.1402.119

Health conditions studied

1

Description of health condition studied
Chronic rhinosinusitis
ICD-10 code
J32.9
ICD-10 code description
Chronic sinusitis, unspecified

Primary outcomes

1

Description
Exhaled nitric oxide level
Timepoint
Before the start of the intervention, immediately after the intervention and one month after the intervention
Method of measurement
Fractional exhaled nitric oxide test with nitric oxide analyzer

2

Description
CT scan score
Timepoint
Before the intervention and one month after the intervention
Method of measurement
Seeing the CT scan stereotype

3

Description
Total score of clinical symptoms
Timepoint
Before the start of the intervention, immediately after the intervention and one month after the intervention
Method of measurement
Sinonasal Outcome Test 22 (SNOT 22) Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the first intervention group, ITO 750 pulsed ultrasound therapy is used.The patient is treated with pulsed ultrasound for 5 sessions every day.In each treatment session, each maxillary sinus for 5 minutes with a dose of 1 w/cm2 and each frontal sinus for 4 minutes with a dose of 0.5 w/cm2, with an applicator with a cross section of 1 cm2 and with circular movements is treated on the surface anatomy of the corresponding sinus. The frequency used in all treatment sessions will be 1MHZ and the pulse time used will be 1ms and the pulse interval will be 9ms.
Category
Treatment - Other

2

Description
Intervention group: In the second intervention group, a low-level Enraf 476 laser is used. Laser treatment is done for 5 sessions every day. The surface of each sinus is divided into 6 points and each point is treated for 33 seconds with an intensity of 1 joule with a point applicator. In total, in each treatment session, each involved sinus is exposed to laser radiation for 198 seconds. . The laser used will be a continuous-type gallium aluminum arsenide diode, with a wavelength of 830 nm, and a power of 30 milliwatts.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
School of Rehabilitation,Tehran University of Medical Sciences
Full name of responsible person
Dr. Noureddin Nakhostin Ansari
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School of Rehabilitation, Tehran University of Medical Sciences, Pich Shemiran, Islamic Revolution St, Tehran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Tehran University of Medical Sciences, Corner of Qods Street, Keshavarz Blvd
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mina Kashi Alashti
Position
Student
Latest degree

Master
Other areas of specialty/work
Physiotherapist
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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
The raw data of the research and its analysis will be provided to the researchers upon their request.
When the data will become available and for how long
After the publication of the articles resulting from the research.
To whom data/document is available
Researchers working in academic institutions.
Under which criteria data/document could be used
The data is provided to other researchers only to study and check the treatment results.
From where data/document is obtainable
Department of Physiotherapy, School of Rehabilitation of Tehran University of Medical Sciences, Islamic Revolution St, Pich Shemiran, Dr.Noureddin Nakhostin Ansari, 09122979309, nakhostin@sina.tums.ac.ir
What processes are involved for a request to access data/document
By sending an official university email to the corresponding author, Dr. Nooruddin Ansari (nakhostin@sina.tums.ac.ir) and requesting documents, a response will be provided as soon as possible.
Comments